

Serial No.: 10/632,061
Examiner: Chris E. Simmons
Group Art Unit: 1609

STATUS OF CLAIMS

Claims 1-27 are presently pending. By this Amendment, Applicant has amended independent claim 1. Support for the amendments to these claims is provided, *inter alia*, in the specification in paragraph [0048] and in the claims as originally filed. Applicant states that there is no issue of new matter.

REMARKS

Rejection Under 35 U.S.C. 102(b) and 102(e)

The Examiner rejected claims 1-7 and 9-26 as being anticipated by Pinchuk (U.S. Pub. No. 2002/0107330 A1).

In response, Applicants respectfully traverse the rejection and their accompanying remarks. Pinchuk does not teach the invention of the claims.

Pinchuk et al. fails to teach all of the elements of the present invention as claimed in independent claim 1, which is directed to a medical device comprising (a) a therapeutic agent and (b) a polymeric release region that controls the release of said therapeutic agent upon administration to a patient, said polymeric release region comprising an acrylic graft copolymer, which comprises (i) a plurality of rubbery acrylic units and (ii) a plurality of hard units.

For a reference to anticipate a claim it must disclose each and every element of the claim. See MPEP 2131 and cases cited therein, especially *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989) and *In re Marshall*, 578 F.2d 301, 304, 198 USPQ 344, 346 (Fed. Cir. 1978). The Pinchuk et al. reference fails as an anticipatory reference because it fails to teach a required element, i.e., an "acrylic graft copolymer."

Pinchuk et al. does not teach any graft copolymers. Rather, Pinchuk et al. teaches various linear and radial block copolymers, including a block copolymer with an "elastomeric block" and a "thermoplastic block." (Pinchuk, paragraph [0027]). Specifically, Pinchuk et al. teaches thermoplastic elastomers having an elastomeric block and phase separated, hard polystyrene blocks, such as a "linear triblock," a "linear alternating block," or a "diblock, triblock and other radial block copolymers" with a polyisobutylene block as the elastomeric and hard polystyrene blocks (see Pinchuk, paragraph [0028] to paragraph [0032]). Pinchuk does not teach a graft copolymer as claimed.

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Thus, Applicant respectfully requests that the Examiner reconsider and withdraw the rejection under § 102(b) or (e) over Pinchuk et al.

Given the above teaching, Applicants respectfully submit that Pinchuk et al. fails to anticipate the invention as claimed. Claim 1 is an independent claim, and the above comments apply directly to it. All other rejected claims are dependent directly on claim 1 and the rejection of those claims fails at least because of the fundamental defect discussed above.

Rejection Under 35 U.S.C. 103(a)

The Examiner rejected claim 8 as unpatentable over Pinchuk in view of Van Dijk et al. (PCT Pub. No. WO 2000/061203). Claim 27 was rejected as unpatentable over Pinchuk in view of Ding et al. (U.S. Pat. No. 5,837,313).

In response, Applicants respectfully traverse the rejection and their accompanying remarks. For the reasons provided above, Pinchuk fails to teach the present invention because it fails to disclose the claimed graft copolymers. The disclosures of Van Dijk et al. and Ding do not remedy the deficiencies of Pinchuk. Neither reference teaches or suggests the claimed acrylic graft copolymers. Rather, Van Dijk et al. teaches all-metal alloy stents ("manufactured from an alloy which contains at least 60% by weight...of one or more metals selected from the group of gold, platinum, palladium, and silver...and an elongation at break of at least 8%"; Van Dijk et al., Abstract). Ding et al. discloses a "thin layer of biostable elastomeric material ...as a coating on the surfaces of a deployable stent prosthesis." (Ding et al., Col. 3, lines 13-17). The elastomeric material is "[f]or example, silicone or polysiloxane materials." (Ding et al., Col. 4, lines 9-10). There is no discussion, suggestion, or appreciation of graft copolymers.

Thus, even if the Examiner argues that motivation exists to combine the teachings in these references, which Applicant asserts does not, such combination would still not result in the claimed invention since all of the elements of the independent claim 1 are not found in the combined references. Not only is there a lack of explicit teaching of the combination, there is simply no reason or suggestion in any of the references for them to be combined to arrive at the present invention. *In re Nilssen*, 851 F.2d 1401, 1403, 7 USPQ2d 1500, 1502 (Fed. Cir. 1988). The lack of teaching, suggestion, or motivation in the references supports Applicant's position that the invention is patentable and non-obvious over the cited art.

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Given the above remarks and the amendments to the claims, Applicant states that the Examiner's rejection under 35 U.S.C § 103(a) has been obviated and Applicant respectfully requests that the Examiner withdraw the rejections.

CONCLUSION

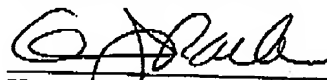
Applicant respectfully submits that all outstanding issues have been resolved and the pending claims are in condition for allowance, early notification of which is earnestly solicited. Should the Examiner be of the view that an interview would expedite the application at large, request is made that the Examiner telephone the undersigned attorney at (908) 518-7700, ext. 7 in order to resolve any outstanding issues. The Office is authorized to charge any fees required to deposit account number 50-1047.

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Respectfully submitted,



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